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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,040	10/16/2006	Atsushi Miyawaki	P28094	3808
7055 7590 08/25/2009 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER KAM, CHIH MIN				
ART UNIT 1656		PAPER NUMBER		
NOTIFICATION DATE 08/25/2009		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com

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### Office Action Summary

**Application No.**

10/561,040

**Applicant(s)**

MIYAWAKI ET AL.

**Examiner**

CHIH-MIN KAM

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.  
4a) Of the above claim(s) 1-7 and 14-22 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 8-13 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 16 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of the Claims***

1. Claims 1-22 are pending.

Applicants' amendment filed June 2, 2009 is acknowledged. Applicants' response has been fully considered. Claims 8-11 have been amended. Claims 1-7 and 14-22 are non-elected inventions and are withdrawn from consideration. Therefore, claims 8-13 are examined.

***Withdrawn Informalities***

2. The previous objection to the specification regarding not providing the "SEQ ID NO:" for the amino acid sequences in Fig. 3 is withdrawn in view of applicants' response at page 11 in the amendment filed June 2, 2009.

***Withdrawn Claim Rejections - 35 USC § 101***

3. The previous rejection of claims 8-13 under 35 U.S.C. 101 is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 11 in the amendment filed June 2, 2009.

***Withdrawn Claim Rejections - 35 USC § 112***

4. The previous rejection of claims 8-13 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment of the claims, and applicants' response at page 12 in the amendment filed June 2, 2009.

***Withdrawn Claim Rejections - 35 USC § 102***

5. The previous rejection of claims 8-13 under 35 U.S.C. 102(e) as being anticipated by Almond *et al.* (U.S. Pub. No. 2003/0157643 A1) is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 12-13 in the amendment filed June 2, 2009.

***Maintained Informalities***

The disclosure is objected to because of the following informalities:

6. The specification does not cite the continuation data for the instant application.

Appropriate correction is required.

***Response to Arguments***

Applicants indicate the instant application is a National Stage application under 35 U.S.C. §371 for PCT/JP2004/08790, and there is no domestic priority claimed for this application.

Applicants' response has been considered, however, the arguments are not found persuasive because while there is no domestic priority claimed for this application, a statement regarding the instant application being a 371 of PCT/JP04/08790, filed June 16, 2004 should be indicated.

***Claim Objections***

7. Claim 8 is objected to because the claim recites a phrase "An isolated DNA a having any of the following nucleotide sequences:". Deletion of the word "a" between "DNA" and "having" is suggested.

***New Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-13 are directed to an isolated DNA having a nucleotide sequence: the nucleotide sequence shown in SEQ ID NO:2, 13, 15, 17, 19 or 21, or a nucleotide sequence comprising a deletion, substitution and/or addition of 1 to 60 nucleotides in the SEQ ID NO:2, 13, 15, 17, 19 or 21; a recombinant vector or a transformant having the DNA; an isolated DNA encoding the amino acid sequence of SEQ ID NO:1, or DNA encoding an amino acid sequence comprising a deletion, substitution and/or addition of 1 to 20 amino acids in the SEQ ID NO:1, and encoding a fluorescent protein; and an isolated DNA having a nucleotide sequence: a nucleotide sequence shown in SEQ ID NO:2, 13, 15, 17, 19 or 21 (reads as full length and fragments of SEQ ID NO:2, 13, 15, 17, 19 or 21), or a nucleotide sequence comprising a deletion, substitution and/or addition of 1 to 60 nucleotides in the SEQ ID NO:2, 13, 15, 17, 19 or 2, and encoding a fluorescent protein.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional

characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification discloses a fluorescent protein from *favia favius* such as SEQ ID NO:1, its specific variants such as SEQ ID NO:12, 14, 16, 18 and 20 having mutations at specific positions, and the nucleotide sequences such as SEQ ID NO:2, 13, 15, 17, 19 and 21 that encoding the fluorescent proteins (pages 2-9 and Fig. 3), the specification does not disclose a genus of variants for polynucleotides having a deletion, substitution and/or addition of 1 to 60 nucleotides in the SEQ ID NO:2, 13, 15, 17, 19 or 21 and encoding a fluorescent protein, or polynucleotide fragments of SEQ ID NO:2, 13, 15, 17, 19 or 21. The specification does not provide sufficient guidance as to what structural differences are permissible in the nucleic acid variant that would still produce a functional protein. While the specification provides SEQ ID NO:2, 13, 15, 17, 19 and 21 as the polynucleotides encoding the fluorescent proteins, it does not provide an adequate written description for the whole genus of polynucleotide variants or fragments that encode fluorescent proteins since there is substantial variation within the whole genus of polynucleotides. Furthermore, there is no sufficient description on structure to function/activity relationship in the disclosed polynucleotide variants. Without guidance for structure to function/activity, one skilled in the art could not predict which portions of the sequence (structure) are essential to produce a functional polypeptide. Given the lack of a

structure to function/activity relationship and lack of representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would not recognize Applicants were in possession of the claimed invention.

***Conclusion***

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

August 18, 2009